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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,640	12/31/2003	Lawrence M. Boyd	1842-0021	9392
7590 Michael D. Beck Suite 3000 111 Monument Circle Indianapolis, IN 46204-5115			EXAMINER HARVEY, JULIANNA NANCY	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 12/23/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/749,640

Applicant(s)

BOYD ET AL.

Examiner

Julianna N. Harvey

Art Unit

3733

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-38 and 41-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-38 and 41-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

37 CFR 1.131 Declaration

The declaration filed on 15 October 2008 under 37 CFR 1.131 has been considered but is ineffective to overcome the Biedermann et al. (US 2005/0154390 A1) reference.

The Biedermann et al. (US 2005/0154390 A1) reference is a U.S. patent or U.S. patent application publication of a pending or patented application that claims the rejected invention (Applicant's claim 36 is the same invention as Biedermann's claim 35). An affidavit or declaration is inappropriate under 37 CFR 1.131(a) when the reference is claiming the same patentable invention, see MPEP § 2300. If the reference and this application are not commonly owned, the reference can only be overcome by establishing priority of invention through interference proceedings. See MPEP Chapter 2300 for information on initiating interference proceedings. If the reference and this application are commonly owned, the reference may be disqualified as prior art by an affidavit or declaration under 37 CFR 1.130. See MPEP § 718.

The evidence submitted is insufficient to establish a conception of the invention (claim 41) prior to the effective date of the Biedermann et al. (US 2005/0154390 A1) reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v.*

Scudder, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). None of the documents submitted mention introducing a device into an intervertebral space in combination with coupling a dynamic stabilization system across the motion segment.

The evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the Biedermann et al. (US 2005/0154390 A1) reference to either a constructive reduction to practice or an actual reduction to practice. MPEP § 715.07 states that "the actual dates of acts relied on to establish diligence must be provided." Furthermore, MPEP § 715.07(a) states that "it is not enough merely to allege that applicant or patent owner had been diligent" and "applicant must show evidence of facts establishing diligence." MPEP § 715.07(a) also directs one to MPEP § 2138.06, which states that the "applicant must account for the entire period during which diligence is required" and cites *Kendall v. Searles* to indicate that "[d]iligence requires that applicants must be specific as to dates and facts." Here, Applicant has redacted dates from documents submitted in an attempt to show diligence. Thus, Applicant has not shown diligence from the time of the alleged conception to Applicant's reduction to practice.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the

invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 36 is rejected under 35 U.S.C. 102(e) as being anticipated by Biedermann et al. (US 2005/0154390 A1). Biedermann et al. disclose a method for dynamic stabilization of the spine comprising the steps of: positioning a stabilization element adjacent the spine, the stabilization element configured to span a length of the spine between two vertebrae; engaging bone anchors to at least two vertebrae; and coupling the bone anchors to the stabilization element, with at least one of the bone anchors coupled to permit deflection of the bone anchor between the stabilization element and the corresponding vertebra to which the at least one of the bone anchors is engaged (paragraphs 0005 and 0098-0102).

Claim 48 is rejected under 35 U.S.C. 102(e) as being anticipated by Ferree (US 2003/0220643 A1). Ferree discloses a method for dynamic stabilization of a motion segment of the spine comprising the steps of: introducing a device into an intervertebral space to at least partially maintain or restore the natural motion of the disc at the motion segment; and coupling a dynamic stabilization system across the motion segment that permits natural motion of the disc and rotation of the motion segment in the anterior/posterior (A/P) plane substantially fully in both directions (paragraphs 0029, 0032, and 0035; Figs. 9A and 9B).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Biedermann et al. (US 2005/0154390 A1) in view of Ferree (US 2003/0220643 A1). Biedermann et al. disclose the claimed invention except the step of repairing or replacing all or part of the intervertebral disc between at least two vertebrae. Ferree teaches a method for dynamic stabilization comprising the step of: repairing or replacing all or part of the intervertebral disc between at least two vertebrae; and coupling a dynamic stabilization system across the motion segment (paragraphs 0032 and 0035; Figs. 9A and 9B). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Biedermann et al. by repairing or replacing all or part of the intervertebral disc between at least two vertebrae, as suggested by Ferree, as in some situations, damage to the disc may require repair or replacement.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Biedermann et al. (US 2005/0154390 A1) in view of Ferree (US 2003/0220643 A1) as applied to claim 37 above, and further in view of Bao et al. (US 5,534,028 A). Biedermann et al. and Ferree teach the claimed invention except that the step of repairing or replacing includes replacing all or part of the nucleus pulposus with a

polymeric prosthesis having physical properties substantially similar to the physical properties of a natural nucleus pulposus. Bao et al. teach a prosthetic nucleus pulposus made of a polymer that has physical properties that are substantially similar to the physical properties of a natural nucleus pulposus (col. 3, lines 13-24). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the Bao et al. prosthetic nucleus pulposus with the Biedermann et al. as modified by Ferree stabilization system as the Bao et al. prosthetic nucleus pulposus allows partial replacement as some situations, such as a herniated disc, may only require replacement of the nucleus pulposus.

Claims 41, 46, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biedermann et al. (US 2005/0154390 A1) in view of Ferree (US 2003/0220643 A1). Regarding **claim 41**, Biedermann et al. disclose a method for dynamic stabilization of a motion segment of the spine comprising the step of: coupling a dynamic stabilization system across the motion segment, the system including at least one bone anchor that permits natural motion of the disc by deforming a portion of the bone anchor (paragraphs 0005 and 0098-0102). Regarding **claim 46**, Biedermann et al. disclose that the bone anchor includes: an engagement portion ("23" in Fig. 3a) configured for engagement within a vertebra of the motion segment; a head portion ("25" in Fig. 3a) configured for engagement to a stabilization element ("100" in Fig. 3a) outside the vertebral body; and a flexible portion ("24" in Fig. 3a) between the engagement portion and the head portion. Regarding **claim 47**, Biedermann et al. disclose that the dynamic stabilization system includes: a stabilization element ("100" in

Fig. 3a) configured to span a length of the spine between at least two vertebrae; and at least two anchors, each of the anchors including a head portion ("25" in Fig. 3a) configured for contacting the stabilization element and an engagement portion ("23" in Fig. 3a) configured for engaging a vertebra, and at least one of the anchors including a flexible portion ("24" in Fig. 3a) between the head portion and the engagement portion. Regarding **claim 41**, Biedermann et al. fail to teach introducing a device into an intervertebral space to at least partially maintain or restore the natural motion of the disc at the motion segment. Ferree teaches a method for dynamic stabilization comprising the steps of: introducing a device into an intervertebral space to at least partially maintain or restore the natural motion of the disc at the motion segment; and coupling a dynamic stabilization system across the motion segment (paragraphs 0032 and 0035; Figs. 9A and 9B). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Biedermann et al. by introducing a device into an intervertebral space to at least partially maintain or restore the natural motion of the disc at the motion segment, as suggested by Ferree, as in some situations, damage to the disc may require replacement.

Claims 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biedermann et al. (US 2005/0154390 A1) in view of Ferree (US 2003/0220643 A1) as applied to claim 41 above, and further in view of Bao et al. (US 5,534,028 A). Biedermann et al. and Ferree teach the claimed invention except that the device includes a device for replacing or augmenting the nucleus pulposus of the intervertebral disc (**claim 42**), that the device is a polymeric prosthesis to replace or augment the

nucleus pulposus in which the polymeric prosthesis exhibits physical properties similar to the natural nucleus pulposus (**claim 43**), and that the polymeric prosthesis is formed of a hydrogel (**claim 44**). Bao et al. teach a prosthetic nucleus pulposus made of hydrogel, a polymer, that has physical properties that are substantially similar to the physical properties of a natural nucleus pulposus (col. 3, lines 13-24). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the Bao et al. prosthetic nucleus pulposus with the Biedermann et al. as modified by Ferree stabilization system as the Bao et al. prosthetic nucleus pulposus allows partial replacement as some situations, such as a herniated disc, may only require replacement of the nucleus pulposus.

Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Biedermann et al. (US 2005/0154390 A1) in view of Ferree (US 2003/0220643 A1) and Bao et al. (US 5,534,028 A) as applied to claim 42 above, and further in view of Fleischmann et al. (US 6,375,682 B1). Biedermann et al., Ferree, and Bao et al. teach the claimed invention except that the device for replacing or augmenting the nucleus pulposus is a mechanical device. Fleischmann et al. teach a mechanical device for replacing the nucleus pulposus (col. 6, lines 43-52). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the Fleischmann et al. mechanical device with the Biedermann et al. as modified by Ferree and Bao et al. stabilization system as the Fleischmann et al. device can be adjusted to fit the individual patient and would also allow for post-operative adjustments (col. 3, lines 19-25 of Fleischmann et al.).

Claims 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferree (US 2003/0220643 A1) in view of Bao et al. (US 5,534,028 A). Ferree discloses the claimed invention except that the device includes a device for replacing or augmenting the nucleus pulposus of the intervertebral disc (**claim 49**), that the device is a polymeric prosthesis to replace or augment the nucleus pulposus in which the polymeric prosthesis exhibits physical properties similar to the natural nucleus pulposus (**claim 50**), and that the polymeric prosthesis is formed of a hydrogel (**claim 51**). Bao et al. teach a prosthetic nucleus pulposus made of hydrogel, a polymer, that has physical properties that are substantially similar to the physical properties of a natural nucleus pulposus (col. 3, lines 13-24). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the Bao et al. prosthetic nucleus pulposus with the Ferree stabilization system as the Bao et al. prosthetic nucleus pulposus is a partial artificial disc replacement designed to preserve spinal motion.

Response to Arguments

Regarding Applicant's remarks concerning the 37 CFR 1.131 declaration and the Biedermann et al. (US 2005/0154390 A1) reference, the Examiner would like to direct Applicant to the section of this Office Action titled "37 CFR 1.131 Declaration", which indicates the reasons that the declaration is insufficient to overcome the Biedermann et al. reference.

Applicant's arguments with respect to the claim 48 rejection over the Ferree (US 2003/0220643 A1) reference have been fully considered but they are not persuasive.

Applicant argues that Ferree focuses on permitting flexion but restricting extension and thus does not contemplate a method in which the natural motion of the disc is preserved as well as the full rotation of the motion segment in the A/P plane (i.e., full extension and full flexion). The examiner respectfully disagrees. First of all, the examiner would like to point out that claim 48 does not preserve full rotation, but merely "substantially" full rotation, of the motion segment in the A/P plane. In rejecting claim 48, the examiner relied on the embodiment of the device shown in Figs. 9A and 9B, which is described in paragraphs 0032 (which refers to Fig. 6D as described in paragraph 0029) and 0035. Paragraph 0032 states that "[t]he L-shaped braces place loads on the sides of the pedicles with spinal extension" and paragraph 0035 states that "[t]he motion preserving embodiments for posterior insertion that allow at least partial spinal flexion while inhibiting at least a certain degree of spinal extension may be particularly suited for use with an ADR." The word "substantially" is a broad term. *In re Nehrenberg*, 280 F.2d 161, 126 USPQ 383 (CCPA 1960). Thus, the Ferree reference contemplates rotation of the motion segment in the A/P plane substantially fully in both directions. Furthermore, the purpose of artificial disc replacement is to mimic a natural disc and thus preserve the motion of a natural disc, which includes flexion and extension of the motion segment.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julianna N. Harvey whose telephone number is 571-270-3815. The examiner can normally be reached on Mon. - Fri., 8:00 a.m. - 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. N. H./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733